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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Klaus Hellerbrand et al.	Examiner:	
Appln. No.:	10/598,698	Group Art Unit:	1618
Filing Date:	September 8, 2006	Confirmation No.:	9077
Title:	COATED IMPLANTS, THEIR MANUFACTURING AND USE THEREOF		
		Customer No.:	25764
		Docket No.:	79650 - 341358

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INFORMATION DISCLOSURE STATEMENT

The materials enclosed herewith are provided to the Examiner for consideration during the examination of the cited patent application. Consideration of each of the documents listed on the attached SB/08 form(s) is respectfully requested.

This Information Disclosure Statement is being filed before the receipt of an Office Action on the merits. No fee is believed to be necessary. However, should any fee be required, the Commissioner is authorized to charge our Deposit Account No. 06-0029 and is requested to notify us of the same.

Respectfully submitted,

FAEGRE & BENSON LLP

By:

Paul W. Busse, Reg. No. 32,403
 612/766-7046
 Customer No.: 25764

Dated: March 23, 2007



F&B (10-06) SB/08a (07-06)

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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				Examiner Name	
Sheet	1	of	5	Attorney Docket Number	79650 - 341358

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 4,051,598	10-04-1977	Sneer	
		US- 4,599,085	07-08-1986	Riess et al.	
		US- 4,882,196	11-21-1989	Shimamune et al.	
		US- 5,011,691	04-30-1991	Oppermann et al.	
		US- 5,258,029	11-02-1993	Chu et al.	
		US- 5,266,683	11-30-1993	Oppermann et al.	
		US- 5,344,654	09-06-1994	Rueger et al.	
		US- 5,697,997	12-16-1997	Aronsson et al.	
		US- 5,934,287	08-10-1999	Hayashi et al.	
		US- 6,113,993	09-05-2000	Gao et al.	
		US- 6,129,928	10-10-2000	Sarangapani et al.	
		US- 6,312,472 B1	11-06-2001	Hall et al.	
		US- 6,322,728 B1	11-27-2001	Brodkin et al.	
		US- 6,419,708 B1	07-16-2002	Hall et al.	
		US- 2003/0204239 A1	10-30-2003	Carlyle et al.	
		US- 6,994,549 B2	02-07-2006	Brodkin et al.	

FOREIGN PATENT DOCUMENTS					
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		EP 0362367 B1	02-28-1996	Stryker Corporation	
		EP 0372031 B1	09-11-1996	Stryker Corporation	
		EP 0389713 B1	04-08-1993	Kyoto University	
		EP 0448704 B1	06-17-1998	Stryker Corporation	
		EP 0467948 B1	01-03-1996	Sifflsen Centrum for Oral Biologi	
		EP 0478532 A1	04-01-1992	Dr. David Thomas	
		EP 0548365 B1	03-31-1999	Kabushiti Kaiysa Advance	
		EP 0575555 B1	07-18-2001	Curis, Inc.	
		EP 0584283 B1	12-15-1991	Intermedics/Orthopedics/ Denver Inc.	
		EP 0601106 B1	05-17-2000	Creative Biomolecules, Inc.	
		EP 0601135 B1	11-02-2005	Curis, Inc.	
		EP 0643767 B1	07-22-1998	Stryker Corporation	
		EP 0646022 B1	09-28-2005	Stryker Corporation	
		EP 0657146 B1	04-01-1998	Nobel Biocare AB	
		EP 0679097 B1	05-28-1997	Genetech, Inc.	
		EP 0714665 B1	01-22-2003	Stryker Corporation	
		EP 0723013 B1	06-18-2006	Stryker Corporation	
		EP 0739191 B1	01-09-2002	Nobel Biocare AB	
		EP 0806211 B1	10-23-2002	IsoTis N.V.	

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		EP 0812207 B1	11-02-2000	Stryker Corporation	
		EP 0972520 B1	08-17-2005	Biopharm.	
		EP 1150725 B1	06-01-2005	SDGI Holdings, Inc.	
		EP 1220693 B1	12-08-2004	Genetics Inst., Inc.	
		EP 1221484 A2	07-10-2002	Stryker Corporation	
		EP 1223990 B1	07-28-2004	Genetics Inst., Inc.	
		EP 1225225 A2	07-24-2002	Stryker Corporation	
		EP 1251889 B1	02-07-2003	IsoTis N.V.	
		WO 198800205	01-14-1988	Genetics Institute, Inc.	
		WO 1992000382	01-09-1992	Carnegie Institution of Washington	
		WO 1993016099	08-19-1993	Biopharm	
		WO 1993000432	01-07-1993	Genetics Institute, Inc.	
		WO 1994010203	05-11-1994	Creative Biomolecules, Inc.	
		WO 1994015949	07-21-1994	Johns Hopkins University School of Medicine	
		WO 1994015966	07-21-1994	Johns Hopkins University School of Medicine	
		WO 1994021681	09-29-1994	Johns Hopkins University School of Medicine	
		WO 1994026892	11-24-1994	Genetics Institute, Inc.	
		WO 1994026893	11-24-1994	Genetics Institute, Inc.	
		WO 1995001801	01-19-1995	Johns Hopkins University School of Medicine	
		WO 1995010539	04-20-1995	Johns Hopkins University School of Medicine	
		WO 1995013101	05-18-1995	Klaas DeGroot	
		WO 1995016035	06-15-1995	Genetics Institute, Inc.	
		WO 1995033830	12-14-1995	Genetics Institute, Inc.	
		WO 1996001316	01-18-1996	Biopharm	
		WO 199601845	01-25-1996	Johns Hopkins University School of Medicine	
		WO 199610370	04-11-1996	Nobelpharma AB	
		WO 1996014335	05-17-1996	The Department of Health and Human Services, US Govt.	

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Translation is attached.
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Substitute for form 1449B/PTO				Complete if Known	
				Application Number	10/598,698
				Filing Date	July 14, 2006
				First Named Inventor	Klaus Hellerbrand
				Art Unit	
				Examiner Name	
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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
		WHARTON et al., "Drosophila 60A gene, another transforming growth factor β family member, is closely related to human bone morphogenetic proteins," <i>Proc. Natl. Acad. Sci. USA.</i> , Volume 88, pp. 9214-9218, 1991			
		SHAH et al., "Mechanism of BMP-2 stimulated adhesion of osteoblastic cells to titanium alloy," <i>Biology of the Cell</i> , Volume 91, pp. 131-142, 1999			
		WOZNEY et al., "Bone Morphogenetic Protein and Bone Morphogenetic Protein Gene Family in Bone Formation and Repair," <i>Clinical Orthopaedics and Related Research</i> , Number 346, pp. 26-37, 1998			
		WOZNEY et al., "Novel Regulators of Bone Formation: Molecular Clones and Activities," <i>Science</i> , Volume 242, pp. 1528-1534, 1988			
		WEEKS et al., "A Maternal mRNA Localized to the Vegetal Hemisphere in Xenopus Eggs Codes for a Growth Factor Related to TGF- β ," <i>Cell</i> , Volume 51, pp. 861-867, 1987			
		VOGGENREITER et al., "Assesment of the Biological Activity of Chemically Immobilized rhBMP-2 on Titanium surfaces <i>in vivo</i> ," <i>Mat.-wiss u. Werkstofftech.</i> , Volume 32, pp. 942-948, 2001			
		UNVERDORBEN et al., "Comparisons of a Silicon Carbide Coated Stent versus a Noncoated Stent in Humans: The Tenax™-versus Nir™-Stent Study (TENISS)," <i>Journal of Interventional Cardiology</i> , Volume 16, Number 4, pp. 325-333			
		TSUI et al., "Plasma sprayed hydroxyapatite coatings on titanium substrates, Part 2: optimisation of coating properties," <i>Biomaterials</i> , Volume 19, pp. 2031-2043, 1998			
		STORM et al., "GDF5 Coordinates Bone and Joint Formation during Digit Development," <i>Developmental Biology</i> , Volume 209, pp. 11-27, 1999			
		SCHNAAR et al., "Adhesion of Chicken Hepatocytes to Polyacrylamide Gels Derivatized with N-Acetylglucosamine," <i>The Journal of Biological Chemistry</i> , Volume 253, Number 21, pp. 7940-7951, 1978			
		SCHMITT et al., "Bone Morphogenetic Proteins: An Update on Basic Biology and Clinical Research," <i>Journal of Orthopaedic Research</i> , Volume 17, pp. 269-278, 1999			
		SAMPATH et al., "Bovine Osteogenic Protein Is Composed of Dimers of OP-1 and BMP-2A, Two Members of the Transforming Growth Factor- β Superfamily," <i>The Journal of Biological Chemistry</i> , Volume 265, Number 22, pp. 13198-13205, 1990			
		PADGETT et al., "A transcript from a <i>Drosophila</i> pattern gene predicts a protein homologous to the transforming growth factor- β family," <i>Nature</i> , Volume 325, pp. 81-84, 1987			
		ÖZKAYNAK et al., Osteogenic Protein-2: A New Member of the Transforming Growth Factor- β superfamily expressed early in embryogenesis,: <i>The Journal of Biological Chemistry</i> , Volume 267, Number 35, pp. 25220-25227, 1992			
		MASSAGUÉ, "The Transforming Growth Factor- β Family," <i>Annu. Rev. Cell Biol.</i> , Volume 6, pp. 597-641, 1990			
		LYONS et al., "Vgr-1, a mammalian gene related to <i>Xenopus</i> Vg-1, is a member of the transforming growth factor β gene superfamily," <i>Proc. Natl. Acad. Sci. USA</i> , Volume 86, pp. 4554-4558, 1989			

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		LIND, "Growth factors: Possible new clinical tools: A Review," <i>Acta Orthop Scand</i> , Volume 67, Number 4, pp. 407-417, 1996			
		ÖZKAYNAK et al., "OP-1 cDNA encodes an osteogenic protein in the TGF-β family," <i>The EMBO Journal</i> , Volume 9, Number 7, pp. 2085-2093, 1990			
		ÖZBEK et al., "Coronary Implantation of Silicone-Carbide-Coated Palmaz-Schatz Stents in Patients With High Risk of Stent Thrombosis Without Oral Anticoagulation," <i>Catheterization and Cardiovascular Diagnosis</i> , Volume 41, pp. 71-78, 1997			
		NISHITOH et al., "Identification of Type I and Type II Serine/Threonine Kinase Receptors for Growth/Differentiation Factor-5," <i>The Journal of Biological Chemistry</i> , Volume 271, Number 35, pp. 21345-21352, 1996			
		LICHTINGER et al., "Osseointegration of Titanium Implants by Addition of Recombinant Bone Morphogenetic Protein 2 (rhBMP-2)," <i>Mat. wiss. u. Werkstofftech.</i> , Volume 32, pp. 937-941, 2001			
		LI et al., "Mineral Dusts Oxidize Methionine Residues: Probable Mechanism of Inactivation of Alpha-1-Antitrypsin," <i>Ann. occup. Hyg.</i> , Volume 41, Supplement 1, pp. 379-383, 1997			
		KATAGIRI et al., "The Non-Osteogenic Mouse Pluripotent Cell Line, C3H10T1/2, is Induced to Differentiate Into Osteoblastic Cells by Recombinant Human Bone Morphogenetic Protein-2," <i>Biochemical and Biophysical Research Communications</i> , Volume 172, Number 1, pp. 295-299, 1990			
		JENNISSEN, "Ultra-hydrophile metallische Biomaterialien," Volume 2, Number 1, pp. 45-53, 2001			abstract included
		HOFMA et al., "Recent Developments in Coated Stents," <i>Current Interventional Cardiology Reports</i> , Volume 3, pp. 26-28, 2001			
		ENDO, "Chemical Modification of Metallic Implant Surfaces with Biofunctional Proteins (Part 1) Molecular Structure and Biological Activity of a Modified NiTi Alloy Surface," <i>Dental Materials Journal</i> , Volume 14, Number 2, pp. 185-198, 1995			
		BROWN, "Incomplete Labeling of Pharmaceuticals: A List of "Inactive" Ingredients," <i>The New England Journal of Medicine</i> , Volume 309, Number 7, pg. 439, 1982			
		CELESTE et al., "Identification of transforming growth factor β family members present in bone-inductive protein purified from bovine bone," <i>Proc. Natl. Acad. Sci., USA</i> , Volume 87, pp. 9843-9847, 1990			
		ALBREKTSSON, "Hard tissue response," <i>Handbook of Biomaterial Properties</i> , Chapter 3, pp. 500-512, 1998			
		BLACKBURN et al., "Carbohydrate-specific Cell Adhesion Is Mediated by Immobilized Glycolipids," <i>The Journal of Biological Chemistry</i> , Volume 258, Number 2, pp. 1180-1188, 1983			
		AMERICAN ACADEMY OF PEDIATRICS, COMMITTEE ON DRUGS, "'Inactive' Ingredients in Pharmaceutical Products," <i>Pediatrics</i> , Volume 76, Number 4, pp. 635-643, 1985			
		International Conference on Harmonization, Topic Q3C, Impurities: Residual Solvents, www.emea.eu.int , March 1998			
		International Search Report and Written Opinion of International Application Number PCT/EP2005/002506, filed March 3, 2005, both mailed September 14, 2005			

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